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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,737	01/06/2000	Patricia D. Wilson	A3275970165.0555	2081

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/06/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/478,737

Applicant(s)

WILSON ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Formal Matters

Claims 1-10 were cancelled, and new claims 21-37 were added in Paper No. 8, 2/15/2002. Claims 21-37 are pending and under consideration.

Claim Objections

Claims 30 and 37 are objected to because of the following informalities: They are dependent on cancelled claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound capable of modulating polycystin-1 activity by measuring the expression of cell adherence to type I collagen coated substrate, apical expression of NaK-ATPase, or expression of β -2-NaK-ATPase, does not reasonably provide enablement for a method for identifying a compound capable of modulating a mutant of polycystin-1 activity by measuring the expression of cell adherence to type I collagen coated

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substrate, apical expression of NaK-ATPase, or expression of β -2-NaK-ATPase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 21-37 are overly broad in the recitation of "mutant" since no guidance is provided as to which of the myriad of polypeptide species encompassed by the claim will retain the characteristics of polycystin-1. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible muteins of polycystin-1. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

Applicant argues that the Specification describes methods for assaying cell adherence to a type I collagen coated surface, NaK-ATPase expression and assaying for incorporation of PKD proteins into focal adhesion clusters, and that coupled with the teachings of the art the methods could be carried out by one of skill in the art.

However, since the term polycystin-1 encompasses mutants (Specification, page 15, lines 13-25), and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to practice the claimed method. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below:

(1) the breadth of the claims - The claims are drawn to a method for identifying a compound capable of modulating a mutant of polycystin-1 activity by measuring the expression

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of cell adherence to type I collagen coated substrate, apical expression of NaK-ATPase, or expression of β -2-NaK-ATPase.

(2) the nature of the invention - The instant invention is a method of compound identification.

(3) the state of the prior art - The Mikayama and Voet references demonstrate that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

(5) the level of predictability in the art - The Mikayama and Voet references demonstrate the unpredictability of the protein art.

(6) the amount of direction provided by the inventor - Applicant has only taught methods using polycystin-1, not mutants of polycystin-1.

(7) the existence of working examples - Working examples are provided only for one polycystin-1, not mutants of polycystin-1.

(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 21-37 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

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Claims 21-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. According to the specification, the term polycystin-1 encompasses mutants and truncated forms of the protein, see page 15, lines 13-25. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to polycystin-1. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, polycystin-1 alone is insufficient to describe the genus. One of skill in the art

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would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "over expressed" in claims 23, 26, 29 and 33 is a relative term which renders the claim indefinite. The term "over expressed" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the metes and bounds of the invention.

The term "increase" in claims 21, 24, 27 is a relative term which renders the claim indefinite. The term "over expressed" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the metes and bounds of the invention. Claims 22-23, 25-26, 28-30 are rejected insofar as they depend on the term "increase".

The term "decrease" in claim 31 is a relative term which renders the claim indefinite. The term "decrease" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the metes and bounds of the invention. Claims 32-37 are rejected insofar as they depend on the term "decrease".

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Claim 21 is vague and indefinite because it encompasses a method of identifying a compound capable of modulating any and all polycystin-1 activities, but the method steps would only identify compounds that increase adherence of cells to type-I collagen. Claims 22-23 are vague and indefinite insofar as they depend on claim 21.

Claim 24 is vague and indefinite because it encompasses a method of identifying a compound capable of modulating any and all polycystin-1 activities, but the method steps would only identify compounds that increase apical expression of NaK-ATPase. Claims 25-26 are vague and indefinite insofar as they depend on claim 24.

Claim 27 is vague and indefinite because it encompasses a method of identifying a compound capable of modulating any and all polycystin-1 activities, but the method steps would only identify compounds that increase expression of beta2-NaK ATPase. Claims 28-30 are vague and indefinite insofar as they depend on claim 27.

Claim 31 is vague and indefinite because it encompasses a method of identifying a compound capable of modulating any and all polycystin-1 activities, but the method steps would only identify compounds that decrease focal adhesion kinase into focal adhesion complexes. Claims 32-37 are vague and indefinite insofar as they depend on claim 31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (1996) in view of Van Adelsberg (1999).

Wilson teaches the correlation between PKD-1 content and degree of adherence to type I collagen. Van Adelsberg teaches peptide inhibitors derived from the PKD repeats of polycystin-1 (page 301, Figure 1). It would have been obvious to one of skill in the art at the time the invention was made to measure adherence of polycystin-1 expressing cells to collagen type-1 in the presence of the inhibitory peptides derived from the PKD repeats of polycystin-1 as taught by Van Adlesberg, with a reasonable expectation of success. One of skill in the art at the time the invention was made would have been motivated to make this modification to determine if type I collagen is a ligand for polycystin-1.

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Conclusion

No claim is allowed.


Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
May 1, 2002



DAVID S. ROMEO
PRIMARY EXAMINER